



**EMBRC workshop,  
Brussels,  
13 September 2016**

# **The EU legal and policy framework for implementation of the Nagoya Protocol**

# Background: international regime

- *Convention on Biological Diversity (CBD, 1992)*
  - **Three objectives**
    - Conservation of biodiversity (within and between species, ecosystems)
    - Sustainable use of its components
    - Fair and equitable sharing of benefits from utilisation of genetic resources (GR)
  - **States' sovereign rights over their natural resources**
    - Authority to determine access to GR
    - Access on mutually agreed terms (MAT), subject to prior informed consent (PIC)
- *Nagoya Protocol to the CBD (NP, 2010=*

# Key characteristics of the EU legal and policy framework for ABS

- *Two pieces of applicable legislation*
  - **'Basic' ABS Regulation** (Reg. 511/2014 – Council & Parliament co-decision)
  - **Implementing Regulation** (Reg. 1866/2015 – Commission with MS experts in ABS Committee)
- *Focus on compliance with Nagoya Protocol*
  - **Access regulation** (if any) → **Member States**
  - **Benefit-sharing** → **contractual arrangements**
- *Direct applicability in all Member States*
- *Voluntary tools to facilitate implementation and compliance*

# EU ABS Regulation – Geographic scope

- *GR/TK from Parties to the Protocol*
  - **Sept. 2016: 80 Parties, incl. EU + 9 MS**  
(CZ, DE, DK, ES, FI, HR, HU, SK, UK – more to follow:  
BE, BG, FR, NL, SE have also ratified)
  - **Non-Party access legislation also to be respected**  
(but not covered by EU Regulation)
- *With (relevant) access legislation in place – info:*
  - **ABS Clearing-House** <https://absch.cbd.int/>
  - **Provider-country's national focal point**
- *Areas beyond national jurisdiction not covered*

# EU ABS Regulation – Temporal scope

- *GR/TK accessed as of NP entry into force (12 October 2014)*
  - **No retro-active effect of EU legislation**
  - **Time of access** (not utilisation) **determines applicability**
  - **Provider-country legislation may diverge**  
(but does not affect temporal scope of EU Regulation)

# EU ABS Regulation – Material scope

- *Genetic resources*
  - **Definition as in CBD**
  - **GR governed by specialised international instruments on ABS excluded from scope**
- *Traditional knowledge associated with GR*
- *Utilisation = research and development*
  - **No legal definition of R&D or lists of activities**
  - **Broad interpretation prevailing (no "salami slicing")**
  - **Commission guidance document(s)**

# EU ABS Regulation – User obligations

- *Exercise due diligence regarding legality of access (and re. sharing of benefits)*
  - **Recognition of users' ability to determine right course of action in a given situation**
  - **Obligation (mostly) of conduct**
- *„Seek, keep and transfer to subsequent users“:*
  - **Information on GR/TK, date/place of access, source, any rights & obligations, PIC & MAT**
  - **Internationally recognised certificate of compliance (IRCC), where available (→ ABS-CH)**
  - **Without sufficient info, discontinue utilisation**

# EU ABS Regulation

## – Member State obligations

- *Designation of competent authorities*
- *Checks on user compliance*
  - **By Member State authorities**
  - **Risk-based approach**
  - **Application of best practice taken into account**
- *Penalties for infringements*
  - **Member State rules (will) apply**
- *Relevant measures pending in many MS*
  - **Commission following up** (infringement proceedings)



# Implementing Regulation – 1st checkpoint for monitoring compliance

- *Due diligence declaration at the stage of research funding*
  - **MS, EC to request the declaration from all recipients of funding** (public or private)
  - **If mixed sources or multiple recipients of funding, declaration required only once** (→ coordinator)
  - **Declaration to be submitted to MS competent authorities** (where user established)

# Implementing Regulation – 2nd checkpoint for monitoring compliance

- *Due diligence declaration at the stage of final development of a product – i.e.:*
  - **When market approval sought**
  - **When notification required**
  - **When placing product on a market** (developed via utilisation of GR/TK)
  - **When result of utilisation sold or transferred for the purpose of one of the above**
  - **When utilisation ended in EU and its outcome sold or transferred outside of EU**

# Facilitating implementation and compliance – EU-wide IT tool

- *For submission of due diligence declarations*
  - **Users to checkpoints** (competent authorities)
  - **Authorities to ABS Clearing House** (relevant parts, after verification)
- *Confidential information*
  - **Submit to competent authorities, marked as such**
  - **Not transmitted to ABS-CH**
  - **Essential info transmitted directly to provider country**
- *Pilot phase starting this autumn*

# Facilitating implementation and compliance – Registered collections

- *EU-wide criteria to be met by collections*
- *Member States verify applications, grant/withdraw recognition, perform risk-based checks*
- *Internet-based register to be established by the Commission (no applications yet)*
- *Users obtaining genetic resources from registered collection considered to have exercised due diligence with regard to seeking of information*

# Facilitating implementation and compliance – Recognised best practices

- *Developed and overseen by association of users or other interested parties*
  - **Role for research infrastructures?**
- *Commission to assess applications, grant recognition, run register of recognised best practices*
  - **3 applications currently pending**
- *Implementation to be taken into account in checks on users*

# Complementary measures

## – Guidance documents

- *Horizontal guidance on scope of the Basic Regulation (Official Journal, 27 August 2016)*
  - **Commission with MS expert support, stakeholder feedback** (Consultation Forum)
- *On-going work on utilisation in different sectors*
  - **Consultancy under EC supervision, with stakeholder input, MS expert support**
  - **Dedicated workstream on research and related "upstream" utilisation** (to be launched)

## Further information

- *Commission DG Environment, ABS website*  
[http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation\\_en.htm](http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm)
- *DG ENV Policy Officers (Unit F3 – 'Multilateral Environmental Cooperation')*
  - [alicja.kozlowska@ec.europa.eu](mailto:alicja.kozlowska@ec.europa.eu)
  - [matthias-leonhard.maier@ec.europa.eu](mailto:matthias-leonhard.maier@ec.europa.eu)
- *CBD Nagoya Protocol website*  
<https://www.cbd.int/abs/default.shtml>